

## Remarks

### I. Introductory remarks

The Applicants acknowledge the withdrawal of the prior claim rejections based on the arguments in the Appeal Brief, which arguments, the Examiner states, have been fully considered and are persuasive, but further that the Examiner has now made new grounds of rejection in view of newly found prior art.

### II. Claim Objections

The Examiner has objected to the lack of text corresponding to claims 23 and 24 in the Appeal Brief, and has requested correction. However, as prosecution on this application has been reopened by the Examiner, and no claim amendments are made in this response, the Applicants would urge that no correction is necessary.

### III. Claim rejections under 37 CFR §103(a)

1. Claims 1-2, 4-5, 7-9 and 11-22 are rejected under 35 U.S.C. §103(a), allegedly, as being unpatentable over Davis *et al.* (WO 92/09266) in view of Nagy *et al.* (US Patent No. 5,871,758) as evidenced by Sakellariou *et al.* (Colloid Polym. Sci. 1995). More specifically, the Examiner suggests that Davis *et al.* (hereinafter “WO’266”) discloses the present invention except for the first liquid phase comprising an oil, although it teaches that the first phase is more lipophilic than water, but that Nagy *et al.* (hereinafter “US’758”) does, and that this combination is supported by Sakellariou. This rejection is respectfully traversed.

WO’266 discloses a composition for topical application to skin comprising two distinct but miscible phases, at least one of which contains a drug. One of the phases contains water and the other is more lipophilic than the water-containing phase. The two phases are intended to be mixed together on or immediately prior to application. On mixing of the two liquid phases, the resulting mixture is supersaturated with respect to the drug. Highly saturated systems are beneficial, since the rate of drug penetration on topical application will depend largely on the degree of saturation. As disclosed in the reference, at page 2, lines 16-22, “It is an inherent property of supersaturated solutions that they will seek to adopt a more thermodynamically stable saturated state. This will generally be achieved by the precipitation of solute from the supersaturated solution. The tendency for precipitation and the time scale over which it will occur

will be dependent on a number of internal external factors..." The reference further discloses that the duration of the supersaturated state is limited by solvent evaporation taking place after mixing together of the two liquid phases, and acknowledges EP 272,045 for the disclosure that the incorporation of an anti-nucleating agent into at least one liquid phase of a supersaturated solution reduces the tendency for drug precipitation. Thus, the compositions in WO'266 include an anti-nucleating agent, such as PVP, which has been found to limit solvent evaporation from the thin film formed after topical administration of the supersaturated drug preparation, thus retaining the integrity of the supersaturated mixture. The anti-nucleating agent can be selected by preparing samples of the desired supersaturated drug solution, adding a selection of anti-nucleating agents, one to each sample, allowing the samples to stand, and noting which samples remain clear.

The Examiner misinterprets "which samples remain clear" to mean that the phases separate. However, from a fair reading of the reference, one skilled in the art would appreciate that "which samples remain clear" refers to which samples remain in the supersaturated or mixed state; that is, where the drug remains supersaturated in the mixture and does not precipitate out. Therefore, there is no phase separation. PVP does not therefore act as a demixing agent in a dual phase composition, as it does in the present invention. One skilled in the art may conclude from the disclosure in WO'266 that PVP is a stabilizing agent, which is its known function, but not a destabilizing or demixing agent.

The Examiner attempts to use Sakellariou to bolster her argument that WO'266 teaches the use of PVP as a demixing agent, commenting that "as evidenced by Sakellariou, PVP is known in the art to cause phase separation (abstract, page 287, left column, second paragraph)". Whether or not that interpretation of Sakellariou is accurate, it does not support the Examiner's position, since, as discussed at some length above, the anti-nucleating agent, PVP, in the compositions of WO'266, cannot be interpreted to demix but only to stabilize the mixed phases state of the supersaturated solution.

The disclosure in US'758 is relied on by the Examiner for the teaching that an oil can be used in a two phase system described in WO'266. The Examiner suggests that it would have been obvious to one of ordinary skill in the art to utilize oils in the first phase as it is disclosed as the more lipophilic phase, and since both references disclose a cosmetic use. Further, one skilled in the art would be motivated to use oil to solubilize oil soluble actives.

The '758 reference addresses the problems encountered in the art in attempting to formulate a liquid dual phase cleansing composition, comprising an oil phase and an aqueous phase, the phases of which are mixed temporarily at the time of use, and which rapidly demix on standing to result in two more aesthetically appealing substantially transparent phases. The

compositions use, as a demixing agent, a specific class of cationic surfactant which is a quaternary nitrogen-containing ether substituted alkoxylated alkyl glucoside. The demixing agent, being water-soluble, is preferably added in the aqueous phase of the composition. The reference does not teach or suggest the Applicants' film formers or their use as demixing agents in a dual phase composition. On the other hand, the WO'266 reference is not at all concerned with compositions which are mixed **temporarily at the time of use and rapidly demixed**. The WO'266 reference instead addresses an entirely different problem which is the instability of a supersaturated solution, in particular a drug-containing supersaturated solution, and the tendency for drug precipitation to occur due to solvent evaporation taking place after mixing together the two liquid phases which comprise the mixed supersaturated solution immediately prior to topical application. The PVP stabilized compositions achieved in the reference are not intended to be demixed but to remain in a clear, supersaturated (mixed) state. The skilled formulator, in attempting to develop a cosmetic cleansing composition which is mixed temporarily at the time of use and rapidly demixed on standing to result in separate transparent phases, would not be motivated to incorporate oil, as taught in US'758, into the compositions of WO'266 for the simple reason that there could be no reasonable expectation of achieving the compositions of the present invention which are temporarily mixed at the time of use and which rapidly demix on standing to result in two transparent phases. The compositions in WO'266 are mixed to form stable supersaturated solutions which do not demix. Incorporating oil and surfactant into those compositions could not be expected to change the nature of those compositions and achieve a composition containing phases which are mixed temporarily at the time of use and rapidly demixed on standing to result in two transparent phases.

2. Claims 3 and 10 are rejected under U.S.C. §103(a), allegedly, as being unpatentable over WO'266 in view of US'758 as evidenced by Sakellariou in further view of Smith (US Patent No. 5,658,559; hereinafter US'559). Specifically, the Examiner contends that the present invention is taught by a combination of the disclosures of WO'266, US'758, and Sakellariou, except for the specific polyvinylpyrrolidone polymer, polyvinyl pyrrolidone hexadecene. For this teaching, the Examiner relies on US'559, suggesting that one of skill in the art would have been motivated to utilize the copolymer in place of the PVP in the modified compositions taught by the combination of references because, as taught in US'559, this copolymer "prevents evaporation loss of moisture from the skin" and WO'266 teaches that "evaporation determines the duration of the supersaturated state", and because PVP and the copolymer are functional equivalents for the purposes of US'559. This rejection, too, is respectfully traversed.

WO'266, US'758 and Sakellariou are discussed above.

US '559 is concerned with formulating an occlusive or semi-occlusive barrier moisturizing lotion useful for treating pathologies of the skin. The lotion is an oil and water emulsion which includes a barrier polymer, for example, PVP or a copolymer of PVP, such as, polyvinylpyrrolidone/hexadecene copolymer. As the lotion dries on the skin, a polymeric film forms on the surface of the lotion which retains the therapeutic agent in place and in intimate contact with the surface of the skin. The occlusive/semi-occlusive nature of the lotion applied to the skin also prevents water evaporation so that the skin becomes hydrated and facilitates the penetration of the drug contained in the lotion into the skin.

For the reasons set out above, the combined teachings of WO'266, US'758 and Sakellariou would not have achieved the dual phase compositions of the present invention. The combination does not result in a dual phase composition which is mixed temporarily at the time of use and rapidly demixed on standing to result in separate transparent phases. Therefore, utilizing PVP/hexadecene copolymer because it is functionally equivalent to PVP in a lotion for forming an occlusive or semi-occlusive barrier film on skin to minimize evaporation of water from the skin, as taught in US'559, in place of the PVP in the modified compositions taught by the combination of WO'266, US'758 and Sakellariou, still would not cure the deficiencies found in the previous combination. Therefore, the Examiner has not made out a *prima facie* case of obviousness and the claims presented are patentable over the combination of cited prior art.

#### IV. Double Patenting Rejection

Claims 1-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,649,174, allegedly since the conflicting claims, although not identical, are not patentably distinct from each other because both sets of claims overlap in scope. The Examiner notes that although a terminal disclaimer has already been filed, on August 1, 2008, in view of the U.S. Patent No. 6,649,174, the form submitted did not identify the patent referenced. The Applicants believe that the form submitted on August 1, 2008 was the official form obtained from the USPTO.gov website, and therefore appropriate at the time of its submission; however, for the avoidance of any confusion, the Applicants now present an updated form which identifies US Patent No. 6,649,174 as the reference patent, together with a copy of the Statement Under 37 C.F.R. 3.73(b) which was previously submitted on August 1, 2008.

## CONCLUSION

The present invention is concerned with a method of demixing a dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase, each phase being separate from the other except when mixed at the time of use, comprising the step of adding to one of the phases of the composition as a demixing agent an effective amount of a non-cationic film forming agent. The Examiner alleges that the present invention is obvious from the combined teachings of WO'266, US'758, Sakellariou, and US'559.

WO'266 is directed to supersaturated, drug-containing solutions, in which PVP is said to function to maintain the transparent mixed, supersaturated state of the solution by reducing the evaporation of water, thereby minimizing the tendency of the drug to precipitate out. Incorporating oils into the WO'266 compositions, as taught by US'758 would not be expected to change the nature of the WO'266 compositions, and therefore could not result in the claimed method in which PVP functions to demix the phases of the dual phase compositions. The teaching in US'559 also would not cure the deficiencies of the modified compositions, since substituting PVP/hexadecene copolymer for the PVP also would not be expected to change the nature of the supersaturated compositions stabilized by PVP. Therefore, the present invention, as defined in claims 1-25, is patentable over the cited references, and it is respectfully requested that the rejections of record be withdrawn and a notice of allowance issued.

In addition to the submission of the terminal disclaimer and requisite fee mentioned above, a petition and fee for extension of time for two months are being submitted concurrently with this paper.

Respectfully submitted,

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